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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/050,359	03/31/1998	DANA M. FOWLKES	FOWLKES-4B	6741

1444 7590 02/19/2002

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 02/19/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory ActionApplication No.
09/050,359Applicant(s)
Fowlkes et alExaminer
Padmashri PonnaluriArt Unit
1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jan 18, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☒ they raise the issue of new matter. (See NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: see the attached sheets.

4. ☐ Applicant's reply has overcome the following rejection(s): _____
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see the attached.
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
Claim(s) allowed: none
Claim(s) objected to: none
Claim(s) rejected: 22, 25-30, and 32-38
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
11. ☐ Other: _____

PADMASHRI PONNALURI
PRIMARY EXAMINER
ART UNIT 1627

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ADVISORY ACTION (continued)

1. The after final amendment and the request for reconsideration filed on 1/18/02 has been fully considered. Applicants have proposed amendments to claims 27, 30, 32, 33, 35 on 1/18/02. The proposed amendments have been considered.

2. Claims 22, 25-30 and 32-38 are currently pending in this application.

Note that claim 31 has been canceled by amendment E, filed on 3/28/01; claims 21 and 23 have been canceled by the amendment C, filed on 5/24/00; claims 1-20 and 24 have been canceled.

3. The after final amendment or request for reconsideration filed on 1/18/02 has not been entered into the application for the following reasons:

The newly proposed amendment **'all peptides of said panel being the same length'** would raise new issues, and may raise new matter rejections. Applicants have not pointed out, wherein the specification has support for this limitations. And the scope of the claims change with the addition of the proposed amendment. The proposed claims require new search with the added limitations. The proposed amendments to the claims do not overcome the rejections of record.

4. Applicants arguments (in response page 5, paragraph 1) regarding claim 31 are moot in view of the cancellation of claim 31, in amendment E, filed on 3/28/01.

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5. Claims 22, 25-30, 32-38 are rejected under 35 U.S.C 101 and 35 U.S.C. 112, first paragraph (UTILITY) for the reasons of set forth in the previous office actions mailed on 12/5/00 and 9/21/01.

Applicant's arguments filed on 1/18/02 have been fully considered but they are not persuasive. Applicants argue that ‘applicants have asserted that their structured panel of combinatorial peptides is useful both directly in the identification of peptides which bind targets and indirectly in the identification of small organic compounds which bind the same target.’ applicants assertions *are* not persuasive because the panel of peptides are only useful in further research (that is to identify small organic compounds or peptides using the instant panel). The peptides in the panel do not have specific utility, and applicants intend to use the peptides in identifying targets or small organic compounds. The organic compounds identified are not known and the utility or function of the identified compounds is not known. Applicants are using the panel (group of peptides) in search of useful compounds. Thus, the research by applicants is to take place at some future time, thus the asserted utility lacks specificity.

Applicants further argue that “a claim to an individual peptide do not meet the utility requirement until a use of the specific peptide was known, e.g., that it bound a target of known biological activity. But we are claiming a structured panel of peptides that has been carefully designed so as to facilitate the identification of target-binding peptides and other target binding molecules. The structured panel of libraries is a research tool.” Applicants arguments have been considered but are not persuasive, because if one single peptide does not meet the utility

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requirement (as stated by applicants), how will a group of such peptides wherein each peptide has no utility, would be considered as having utility.

Applicants further argue that ‘the ultimately useful compound is the one from the ‘complementary library, not the original library. Thus, one could screen a peptide library to find peptides that bind to the target, and then screen a benzodiazepine library for benzodiazepines that inhibit the binding of the peptide to the target.’ Thus, the peptides in the library are not known to be useful. So the benefit to the public (to one of ordinary skill in the art) is speculative. The library of peptides are used to identify benzodiazepine library. The library of peptides of the instant claims are not known to be biologically active, and they are only used to identify potential candidates (benzodiazepines in a library) that inhibit the binding of the peptide to the target. In this method, first, peptides that bind to a target have to be identified, and thus identified peptides are further used to identify benzodiazepines in a library. Thus, the instantly claimed peptides have no utility, but they are used in future research to identify potentially active benzodiazepines. Thus, in the future, may be a biologically active compound may be identified. The biomedical research contemplated by applicants is to take place at some future time, only when the properties of the claimed compounds have been elucidated by the experimental methods (if the peptides bind to target) to which the specification alludes. Absent a disclosure of those properties, the asserted utility of ‘structured panel as a research tool’ lacks specificity.

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Applicants arguments regarding the use of language 'kit' has been considered but is not persuasive, since the kit comprising components, which do not have utility, would not be considered as meeting the requirements of 'utility'.

Applicants arguments regarding 'commercial success' is not persuasive, because the libraries sold are used in further research to identify specific proteins, and wherein the libraries are defined, and those libraries are different from the instantly claimed libraries. The rejections of record have been maintained for the reasons of record.

6. Applicants arguments regarding 35 U. S. C. 112, first paragraph rejection of claims 22, 25-30, have been considered. This rejection has been maintained, since the specification page 25, discloses a specific peptide sequence. The specification disclosure does not relate to the structured panel of the instant claims. The rejections have been maintained for the reasons of record.

7. Applicants arguments regarding 35 U. S. C. 112, second paragraph rejections.

A) Applicants arguments regarding term 'fixed' in the claims has been considered. But the arguments are moot in view of cancellation of claim 31, by the amendment **E, filed on 3/28/01**.

And the arguments regarding the use of the term in other issued patents is not relevant, since the each application is examined on its merits. In the absence of peptide sequence, the arbiter determinations from the ends of the peptide sequence the term 'fixed' is indefinite. The rejections have been maintained for the reasons of record.

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B) Applicants arguments regarding the 'structured panel' would be considered upon entry of the amendment into the claim. The rejection has been maintained.

C) Applicants arguments regarding the terms 'first' and 'second' would be considered upon entry of the amendment into the claim. The rejection has been maintained.

8. Applicants arguments regarding the art rejections have been considered, but are not persuasive.

A) Applicants argue that the rejection of claims 22, 25, 28-29 over Pinilla et al is not proper. Applicants argue that *'Claims 21 and 23 were replaced with new claims 31 and 32, which were not rejected over Pinilla. Claims 22 and 25-27 were amended May 24, 2000 to be dependent on claim 31. Claims 28 and 29 are dependent, through 23 on 31. However, claim 31 has not been so rejected.'*

Examiner respectfully disagrees with applicants, since claim 31 was canceled by the amendment E, filed on 3/28/01.

(i.e., See page 1, of the office action mailed on 9/21/01. (9. Claim 31 has been canceled by amendment E, filed on 3/28/01; claims 21 and 23 have been canceled and new claims 31-38 have been added by the amendment C, filed on 5/24/00; claims 1-20 and 24 have been canceled and new claims 25-30 have been added by the amendment B, filed on 9/29/99.

10. *Claim 22 has been inadvertently not included as pending claim in the previous office action. Examiner regrets if this caused any confusion.*

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It is noted that in page 5 of response filed on 3/28/01, applicants have mentioned that 'claims 25-30 and 32-38 now are pending.' However, the amendment includes amended claim 22. For compact prosecution claim 22 has been examined in this application.) However, these rejections were not addressed in the previous responses filed on 3/28/01. Applicants response filed in 1/18/02 is moot in view of cancellation of claim 31.

B) Applicants arguments regarding the rejection of claims 22, 25, 28-29 over Hoffmann et al has been considered. Upon entry of the amendment, the rejection *may be withdrawn.*

C) Applicants arguments regarding the rejection of claims 32-38 over Spatola et al have been considered. Applicants argue that 'first position is fixed for all libraries in the panel', which is interpreted as 'all the first positions in all the libraries of the panel is fixed.' And the recitation of 'But the libraries of the panel collectively present a plurality of different residues at said first position...', is not considered as a limitation, since it is not possible to have a fixed position, which varies. Applicants arguments regarding the 'Spatola's fixed position is outside the middle 50 %' has been considered. But is not persuasive for the reasons of record over 'middle 50 %'. Moreover, the claim recites that 'wherein the first position is (a) at least five amino acids from both ends of the peptides, or (b) is in the middle 50 % of the peptides...', thus, Spatola's Asp at position 5 can read on the at least 5 amino acids from both ends of the peptides or in the middle if the peptides are cyclized. It is noted that the instant claims recite linear

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peptides however, Spatola prepares linear peptides and cyclizes. The rejections have been maintained for the reasons of record.

Any inquiry concerning this communication should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached at (703)308-2439. The fax number for this group is (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

P. Ponnaluri
Patent Examiner
Technology center 1600
Art Unit 1627


PADMASHRI PONNALURI
PRIMARY EXAMINER